

DEPARTMENT OF THE ARMY  
HEADQUARTERS, UNITED STATES ARMY MEDICAL COMMAND  
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MEDCOM Regulation  
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Medical Services  
**THE PATIENT SAFETY PROGRAM**

Supplementation of this regulation and establishment of forms other than MEDCOM forms are prohibited without prior approval from HQ MEDCOM, ATTN: MCHO-Q.

**1. HISTORY.** This is the first printing of this publication.

**2. PURPOSE.** This publication--

a. Establishes an Army Medical Department (AMEDD) Patient Safety Program (PSP) to identify and centrally report actual and potential problems in medical systems and processes and to improve patient safety (PS) and health care quality throughout the AMEDD.

b. Establishes a Patient Safety Center (PSC) at the U.S. Army Medical Command (USAMEDCOM) to facilitate identification, management, communication, coordination, and teamwork in corporate PS systems and process improvement initiatives.

c. Establishes procedures for every military treatment facility (MTF) to execute a dedicated program for avoiding patient harm and improving PS.

d. Defines processes, within the MTF performance improvement structure, for assessing high-risk functions/processes; reporting, reviewing and analyzing risk and safety data; and initiating corrective measures to reduce and prevent future occurrences.

e. Supports the use of a standardized PS event reporting process; corporate database; and methodology for collecting, aggregating, and analyzing both individual MTF as well as corporate PS data.

f. Establishes a standardized method for categorizing PS events based on event severity and probability of recurrence.

g. Establishes a standardized methodology for conducting aggregate and root cause analyses (RCA) and documentation of action plans for improvement.

h. Clarifies the types of PS events and/or professional behaviors requiring evaluation and management through established individual peer/performance review processes.

i. Provides guidance for implementation of Department of Defense (DOD) Instruction (DODI) 6025.17 and the requirements for confidentiality of medical quality assurance (QA) records under Title 10, United States Code (USC), Section 1102 (10 USC 1102) and DOD Directive 6040.37.

**3. REFERENCES.** Required and related publications are listed in appendix A.

**4. EXPLANATION OF ABBREVIATIONS AND TERMS.** Abbreviations and special terms are explained in the glossary.

**5. APPLICABILITY.** This regulation applies to personnel in all USAMEDCOM installations and activities.

**6. RESPONSIBILITIES.**

a. The Commander, USAMEDCOM/The Surgeon General (TSG), as the senior medical officer in the Department of Army, will--

(1) Establish policy and standardized procedures to implement DODI 6025.17 and facilitate the safe delivery and quality of health care provided to all categories of beneficiaries.

(2) Promote a blameless culture through active support of the AMEDD PSP and communication of PS principles throughout all levels of the organization.

(3) Allocate resources required to initiate and sustain a comprehensive AMEDD PSP.

(4) Support establishment of a standardized AMEDD PS database and MTF reporting requirements for effective program monitoring and evaluation.

(5) Delegate to MTF commanders the responsibility and accountability for implementation and sustainment of the PSP within their MTFs.

b. In accordance with DODI 6025.17, the Military Health System Patient Safety Center at Armed Forces Institute of Pathology (AFIP) will--

(1) Identify effective strategies/actions to improve PS and health care quality throughout the military healthcare system (MHS).

(2) Prepare and distribute MHS quarterly PSP reports (see DODI 6025.17) and lessons learned to the Office of Assistant Secretary of Defense for Health Affairs (OASD(HA)), the Secretaries of the Military Services, the Surgeons General, the President of the Uniformed Services University of the Health Sciences, and all DOD MTFs.

c. The USAMEDCOM Staff Judge Advocate will provide legal interpretation of and guidance related to the contents and application of this regulation.

d. The USAMEDCOM Quality Management (QM) Directorate patient safety team (PST) will--

(1) Exercise broad oversight responsibility for development and implementation of the AMEDD PSP as delegated by TSG.

(2) Represent TSG as a member of various committees and working groups sponsored by OASD/HA, DOD, and other health care agencies.

(3) Educate and train MTF patient safety managers (PSMs) and other commander-selected individuals on all aspects of the AMEDD PSP.

(4) Provide advice, assistance, and ongoing feedback to the MTF staff in identifying and categorizing PS events, conducting aggregate reviews and RCAs, and developing appropriate action plans for process/system improvement.

(5) Provide tools to facilitate implementation of standardized PS processes and metrics to monitor and evaluate program compliance and effectiveness.

(6) Collect, maintain, analyze, and report aggregate PS data as required by the OASD/HA, DOD, and other agencies.

(7) Maintain the AMEDD PS database and submit MTF-specific information and reports regarding PS events, RCAs, action plans, and aggregate data to the AFIP PS registry per current DOD guidance.

(8) Monitor AMEDD PS trends and report the results to both internal and external sources, as appropriate.

(9) Publish "lessons learned" from reported AMEDD PS data to facilitate implementation of risk reduction strategies and promulgate evidenced-based best practices/safe practice methodologies (hereafter referred to as best/safe practices) throughout the AMEDD.

e. Regional Medical Command (RMC) commanders are/will--

(1) Responsible for effective implementation of the AMEDD PSP in their subordinate units.

(2) Assist the USAMEDCOM PSC with execution of the AMEDD PSP and PS training within the region.

f. The Commander, U.S. Army Medical Department Center and School, will--

(1) Facilitate programs of instruction that contain content relevant to the current AMEDD PSP and health care facility accreditation PS standards.

(2) Ensure that curriculum instruction emphasizes the responsibility that each member of the AMEDD has to participate in PS activities.

g. MTF commanders are/will--

(1) Responsible for effective implementation and compliance with AMEDD PS policy as defined in this regulation.

(2) Promote a culture that emphasizes cooperation and communication, encourages reporting of medical errors, focuses on error prevention rather than punishment, and improves medical systems and processes to overcome preventable errors.

(3) Designate an individual, with strong clinical and systems analysis background, as the PSM to direct the organization-wide PSP.

(4) Allocate the resources required to sustain a comprehensive, integrated PSP according to the provisions of this regulation.

(5) Promote strategies to encourage and facilitate staff identification and reporting of close calls/near misses and actual PS events.

(6) Designate membership of the PS committee/functional team responsible for support and oversight of all PS activities.

(7) Ensure all assigned staff are educated on AMEDD PSP components, roles/responsibilities, as well as effective communication, coordination, and teamwork techniques.

(8) Facilitate the education of MTF beneficiaries regarding their roles and responsibilities as partners in the health care process, to include the identification of PS-related issues.

h. Deputy commanders (e.g., deputy commander for clinical services (DCCS), deputy commander for nursing (DCN), or deputy commander for administration (DCA)) are/will--

(1) Responsible for oversight of the PSP and serve as chairperson of the interdisciplinary MTF safety committee/functional team (also see paragraph 9).

(2) Ensure that PSP activities are implemented, monitored, and evaluated for effectiveness according to this regulation.

(3) Support an organizational culture that emphasizes cooperation and communication, encourages reporting of potential and actual PS events, focuses on error prevention rather than punishment, and improves medical systems and processes to overcome preventable errors.

(4) Facilitate orientation and ongoing education of all staff regarding their roles and responsibilities.

(5) Promote support/assistance to staff members involved in a sentinel event (SE).

(6) Ensure that a qualified health care professional informs the patient or family member(s), according to the provisions of this regulation, when a PS event results in an unanticipated outcome of care.

i. Chief, department/service/clinic and management/supervisory staff will--

(1) Ensure PSP activities are implemented, monitored, and evaluated for effectiveness and actively participate in these processes.

(2) Support a culture at the department/service level that emphasizes cooperation and communication, encourages reporting of potential and actual PS events, focuses on error prevention rather than punishment, and improves medical systems and processes to overcome preventable errors.

(3) Facilitate orientation and ongoing education of all assigned staff regarding their roles and responsibilities in the PSP.

(4) Actively participate and facilitate the acknowledgement of reports and timely feedback to individuals (staff, patient, family, visitors) who report PS events.

(5) Facilitate coordination, integration, and implementation of inter/intradepartmental PS initiatives.

(6) Make recommendations for improving PS to the PSM and/or MTF PS committee/functional team.

(7) Promote support/assistance to staff members involved in SEs.

(8) Designate a qualified health care professional to inform the patient or family member(s), according to the provisions of this regulation, when a PS event results in unanticipated outcome of care.

(9) Ensure that staff members educate patients/family members on their roles and responsibilities related to the safe delivery of care.

j. Chief, Logistics and Pharmacy Division will, in addition to the responsibilities defined for department chiefs, facilitate notification of the PSM and appropriate department/service chiefs regarding all product liability complaints/recalls.

k. Patient safety manager. The PSM, or a similarly titled individual, is tasked with the coordination of the organization's PSP. The individual in this role may be expected to exercise broad oversight and to collaborate with various key staff to ensure the effective integration of the PSP functions by the organization. The PSM should be included in all activities involving PS issues. His/her membership on the MTF executive leadership team is encouraged. He/she will--

(1) Manage and facilitate the successful implementation and sustainment of the AMEDD PSP within the organization, according to this regulation.

(2) Provide expertise and guidance to staff members in the areas of risk assessment, prospective analyses, aggregate analyses, RCA, and the development and evaluation of action plans.

(3) Serve as the MTF liaison to the USAMEDCOM PSC.

(4) Coordinate, facilitate, and/or educate all MTF-assigned personnel on their roles and responsibilities in the PSP, to include reporting of all PS events, participating in MTF PS activities, and educating patients/families regarding all aspects of the safe delivery of care.

(5) Ensure that both MTF staff and beneficiaries are surveyed, according to current DOD guidance, to determine their perceptions of PS within their health care organizations. The PSC will provide the survey tool and instructions for its use.

(6) Implement a process to receive and centrally manage all PS event reports from clinical and administrative staff and/or patients and families.

(7) Evaluate each PS event report, either independently or as part of an MTF-level team and, based on the assigned safety assessment code (SAC), determine the appropriate level of review or analysis required.

(8) Acknowledge the receipt of PS reports and provide timely feedback to staff members who submit PS reports and/or plans for process/system improvements.

(9) Oversee the investigation of all SEs to ensure coordination of all data collection activities, completion of a thorough and credible RCA, development of an action plan, and required reporting through channels to the appropriate agency(ies).

(10) Ensure that PS action plans are implemented, evaluated for effectiveness, and communicated both internally and to the appropriate external organizational entities.

(11) Maintain the PS database and submit information and reports regarding PS events, RCAs, action plans, and aggregate data to the MTF PS committee/functional team and USAMEDCOM PSC.

(12) Review, aggregate, and analyze reports of all close calls, adverse events, and SEs--to include written findings and recommendations for improvements in systems and processes--to reduce the frequency and severity of patient harm.

(13) Serve as a member of the MTF PS committee/functional team and provide the committee, as well as all levels of staff, information regarding MTF, corporate, and nationwide PS alerts, updates, and initiatives.

(14) Present opportunities for improvement related to organizational risk assessment(s), with recommendations for identified risks, implementation plans, and follow-up activities to the MTF PS committee/functional team and USAMEDCOM PSC for action.

(15) Oversee the education of the beneficiary population regarding the role of patients/family members in the identification of PS-related issues.

(16) Ensure effective feedback to appropriate personnel on lessons learned and process/system improvements that have been or will be initiated.

l. The MTF safety and occupational health manager will serve as a voting member on the PS committee/functional team and serve as an active PST participant.

m. All MTF personnel will--

(1) Fully understand and take responsibility for their own roles in the PSP.

(2) Actively participate in creating a safe environment for themselves, peers, patients, and families by meeting organizational and professional standards, following identified best/safe practices, and proactively mitigate unsafe conditions or situations.

(3) Complete organization/unit-based orientation and participate in ongoing education, per organizational policy, related to the AMEDD PSP and all MTF PS activities.

(4) Voluntarily report all close calls/near misses, adverse events, and/or SEs.

(5) Initiate immediate steps to ensure patient and staff safety and secure any supplies/equipment that may have precipitated a PS event in order to prevent and/or mitigate future patient harm. If the event was caused or exacerbated by a supply or equipment problem, initiate a medical materiel complaint in accordance with AR 40-61. Submission of this complaint also satisfies the reporting requirement of the Safe Medical Devices Act of 1990.

(6) Educate patients/families in their roles and responsibilities to facilitate the safe delivery of care.

(7) Remain informed of recommended successful best/safe practices and safety alerts.

## **7. General.**

a. PS involves a variety of clinical and administrative activities that health care organizations undertake to identify, evaluate, and reduce the potential for harm to beneficiaries and to improve the quality of health care. Effective medical/health care error reduction requires an integrated approach and a supportive environment in which patients, their families, organization staff, and leaders can identify, manage, and learn from actual and potential risks.

b. A successful PSP facilitates a non-punitive, interdisciplinary approach to decrease unanticipated adverse health care outcomes. The organizational focus is on continued learning about risks and mitigation strategies and reengineering systems/processes to reduce the chance of human error. The AMEDD fosters and supports an organizational environment that recognizes and acknowledges potential risks to PS and the occurrence of medical/health care errors. The PSP encourages medical error reporting in order to identify system or process failures and to enhance improvement strategies.

## **8. THE AMEDD PSP.**

a. The goal of the AMEDD PSP is to reduce the chance that the adverse effects of human error will harm patients. By creating and promoting a culture in which staff willingly report actual and near-miss PS-related events without fear of disciplinary action, the AMEDD is encouraging these events to be freely identified. Once events have been identified, systems and processes can be analyzed and improved in order to



prevent future recurrence. Improved systems and processes result in a safer patient care environment.

b. The AMEDD PSP focuses on system and process design rather than on the individual involved in a given PS-related mishap. This paradigm is very different from that which currently prevails in the AMEDD and in the health care community at large. In the PS-conscious culture, when an error occurs the response is not to ask "who," but rather "why." This new paradigm can exist in light of other organizational expectations associated with risk management (RM), claims management, and review of potentially compensable events (PCEs) for which the Government may incur financial liability.

c. For all PCEs current regulatory guidance (AR 40-68) requires that an investigation be conducted to determine the cause(s) of the adverse event. In all paid medical malpractice claims, current legal statutes dictate that the professional practice of the significantly involved provider/professional will be reviewed to determine if the standard of care (SOC) was met. This RM review/reporting process involving the National Practitioner Data Bank and other regulatory agencies is likewise delineated in AR 40-68. While the PSP and RM processes are both protected under 10 USC 1102, each has its unique intent and focus.

d. A PS event that causes no patient harm requires no SOC determination. However, any PS event that results in patient harm, by definition, is a PCE. The risk manager will be notified of all PCEs and these will be managed according to the RM guidance in AR 40-68. Given the results of the QM investigation of the event, an SOC determination may be required. It may be appropriate and expedient to conduct the PS activities and SOC determination simultaneously, as separate but parallel activities. Competence-related information that arises through PS investigations will not be released outside the PSP except as noted in paragraph e below. The PSP will consider process/system issues, while the SOC determination reviews the individual's performance.

e. Although not a specific focus of the PSP, concerns about a specific provider's/professional's competence may arise. Competence relates directly to an individual and, as such, requires an evaluation of the provider's/professional's performance, not an evaluation of the health care system. Competence will be addressed through the organization's competence assessment, credentialing, and privileging processes. No individual competence-related information will be released outside the PSP, except as noted in paragraph f below. If the competency assessment processes are determined to require review and improvement, such recommendations by the PS committee/function may be appropriate.

f. The vast majority of errors are unintentional. No disciplinary action will be initiated against the individual(s) involved in an unintentional error. However, certain events, as noted below, do warrant administrative, disciplinary, or legal action. Should any of the following be discovered in the course of a PS event evaluation, the MTF commander

will be immediately informed of the circumstance; action taken is beyond the scope of the MTF PSP:

- (1) Criminal activity (e.g., rape, assault and battery, homicide, etc.).
- (2) Intentional unsafe acts due to gross negligence or reckless behavior.
- (3) Alleged patient abuse of any kind.
- (4) Impairment due to medical and psychological conditions including alcohol or other drug abuse.

**9. THE MTF PS FUNCTION.** Integration of all PS-related issues and processes under the auspices of a single committee/functional team is required. This reduces duplication of effort and enhances program efficiency.

a. **Membership.** The MTF PS committee/functional team membership will be multidisciplinary in its composition and include, as a minimum, selected leaders of the organization (e.g., the DCCS, DCN, DCA), or their respective representatives; the PSM; QM/performance improvement coordinator; risk manager; MTF safety and occupational health manager; as well as a cross-section of staff members who are empowered to influence organizational change in order to reduce harm to patients. Other participants may include the command sergeant major or representative; the patient representative; and a representative from pharmacy, logistics, infection control/preventive medicine, hospital education, and the office of the center judge advocate (OCJA)/office of the staff judge advocate (OSJA). Selected department/service chiefs, functional team leaders, and a community representative should also be considered for membership and/or consulted, as needed.

b. **Chairperson.** A senior, command-selected representative will chair the committee/function.

c. **Committee/function minutes/reports.**

(1) The PS committee/functional team minutes or reports will summarize the MTF's PS activities to include, as a minimum--

(a) Aggregation and analyses of all clinical and non-clinical-reported events, trends, and lessons learned.

(b) Actions necessary for organizational process/system improvements, as appropriate.

(c) Proactive PS error reduction activities.

(d) Progress related to organizational risk assessments, prospective analyses, and RCA action plan implementation and effectiveness, according to established timelines.

(2) The PS committee/functional team minutes or reports will be maintained according to AR 25-400-2.

(3) The PS minutes/reports are forwarded to the MTF executive committee. Recommendations associated with PS are considered and prioritized with other organizational system/process improvement actions, as appropriate.

**10. THE PS ORGANIZATIONAL ASSESSMENT.** PS encompasses complex, multidisciplinary processes. It is recommended that each health care organization systematically assess its high-risk organizational systems/processes to identify and prioritize safety improvement requirements. High-risk services/areas include, but are not limited to anesthesia, dialysis, emergency services, intensive care, obstetrics, the operating room, pharmacy, psychiatric treatment, radiology, and transfusion services.

a. PS organizational assessment facilitates the health care organization's evaluation of its current safety program and its various components as well as current policies and procedures, and, as a result of this evaluation, the MTF's PS improvement strategies can be appropriately prioritized.

b. Each MTF will perform an organizational PS assessment annually, according to its performance improvement priority schedule, using the measurement tool(s) provided by the USAMEDCOM PSC.

c. Other appropriate PS assessment activities may include reviewing internal (i.e., AMEDD organizations) and/or external data reports to identify high-risk areas for organizations of similar size and patient populations. External sources of information include, but are not limited to, the Joint Commission for the Accreditation of Healthcare Organization (JCAHO) SE report information; ORYX (see terms in glossary) core measures and performance data; occurrence reporting from State, national, and Federal sources; and the current literature.

d. Annual PS assessment activities may identify more than one organizational high-risk process improvement need. The PS committee/functional team will document and recommend to the MTF executive committee the high-risk process improvement priorities. The executive committee will select one high-risk process and ensure completion of a prospective analysis per current accreditation standards/methodologies and current USAMEDCOM guidance.

e. Any additional high-risk processes that have been identified will be prioritized and included in the MTF performance improvement annual plan. Formal analyses and improvement strategies for these process improvements will be completed per availability of appropriate organizational resources.

## **11. MANAGEMENT OF PS INFORMATION.**

a. The focus of PS data collection and reporting in the AMEDD is to improve organizational systems and to provide the safest care possible to DOD beneficiaries. The PS data reporting processes will be standardized across the organization and will include and leverage existing corporate databases (i.e., MedMARx).

b. In an effort to examine trends in reported events across the AMEDD, each MTF will systematically collect USAMEDCOM-identified PS event core data elements as a minimum. Standardized core data elements to accurately capture PS-related events will allow each MTF and the USAMEDCOM the opportunity to track and trend aggregate data for effective analyses.

c. Data trend analyses will include, but not be limited to, the following:

- (1) Medication errors and falls.
- (2) Equipment malfunctions.
- (3) Events categorized by severity per SAC methodology.
- (4) Preventive/corrective interventions implemented.

d. Customized ad hoc queries and reports will be developed as directed by the USAMEDCOM PSC-published schedule. These may be requested from the PSM by internal MTF or external DOD sources.

e. Detailed data analyses of data using the query and reports capabilities will provide useful information to any level of management. This information will highlight the various contributing factors associated with PS events and facilitate decision-making regarding the specific process improvements required to prevent recurrence.

## **12. PS EVENT MANAGEMENT.**

a. Event identification. A PS event is any incident that occurred (actual event) or almost occurred (close call/near miss) that caused or had the potential to cause harm to a patient. Identification and reporting of close calls and adverse events, including those that result from practitioner error, should be encouraged as an expectation of everyday practice. The three types of PS events include close calls/near misses, adverse events, and SEs.

(1) Close call/near miss. A close call is an event or situation that could have resulted in harm to a patient, but did not, either by chance or through timely intervention. The event was identified and resolved before reaching the patient. Such events have also been referred to as “near miss” incidents. Because close calls generally occur

more frequently than actual adverse events, proactive analyses of close calls provide a tangible opportunity to improve the system without having to experience an actual adverse event. Leaders should emphasize the value of close calls and encourage and acknowledge staff for reporting these opportunities for improvement.

(2) Adverse event. An adverse event is an occurrence associated with the provision of health care or services that may or may not result in harm to the patient/beneficiary. Adverse events may be due to acts of commission or omission. Incidents such as patient falls or improper administration of medications are also considered adverse events even if there is no harm or permanent effect on the patient.

(3) Sentinel event. An SE is an unexpected occurrence involving death, serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof," includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and proactive response on the part of the organization.

b. Event documentation and internal reporting. Prevention of harm to patients is everyone's responsibility and reporting all potential and/or actual PS events is a performance expectation for all MTF-assigned staff. Anyone with knowledge of a PS event not only may, but should, report it.

#### (1) Immediate actions.

(a) Upon identification of an actual PS event, the staff member will immediately perform necessary health care interventions to protect and support the patient's clinical condition. The patient's attending physician and other physicians, as appropriate, will be contacted as soon as possible to report the incident and to provide an update on the patient's current clinical status.

(b) As appropriate to the event, the staff member will initiate all physician-directed orders and take other necessary health care interventions to contain the risk to others, and to preserve event-related materials that may require further investigation. Examples of physical information preservation include: removal and preservation of a blood unit for a suspected transfusion reaction; preservation of IV tubing, the fluid bag, and/or IV pump for a patient with a severe drug reaction from IV medication. Preservation of information also includes documenting the facts regarding the event in the patient's medical record according to organizational policy and procedure.

(c) If the PS event involves serious physical or psychological injury, unexpected death, or qualifies as an SE that is reviewable by the JCAHO, the appropriate department/service chief and the nursing supervisor will be notified immediately. If such PS events occur after hours, the administrative officer of the day will be notified immediately. Individuals notified will ensure proper notification of designated members of the MTF senior leadership.

(2) Documentation and internal reporting. Any individual in any department who identifies a potential (e.g., close call) or actual PS event will immediately notify his or her supervisor and will initiate an incident report. This report will contain concise, factual, objective, and complete details about the event. While explanation of the event is appropriate to include precipitating circumstances or reasons, speculation about factors that contributed to the event should be avoided.

(a) Incident reports will be forwarded to the staff member's unit, clinic, and/or department manager, as appropriate, within 24 hours of discovery of event or on the first duty day following a weekend or holiday. The manager/supervisor will review the document, add any additional relevant information, and forward it to the MTF PSM within 24 hours of receipt.

(b) The MTF PSM, or designee, will review all incident reports and assign a SAC (appendix B). In addition, the PSM will determine what specific actions are necessary to further evaluate SAC 2 events. If the PS event is a SAC 3, the PSM will immediately notify the MTF commander and a root cause analysis team (RCAT) will be chartered. The PSM will also enter the information from the incident report into the MTF PS database.

(c) If a PS event is an intentional unsafe act that results from gross negligence or possible criminal activity, the event shall be reported to the appropriate authorities for investigation. Such an event will not be managed under the auspices of the MTF PSP regardless of the SAC score. (See paragraph 8f for additional information.)

(d) Some events fall within the definition of both an adverse event and an intentional unsafe act. For example, an infant abduction would be both a crime and a JCAHO-reportable SE that requires an RCA. In cases that appear to be both an adverse event and an intentional unsafe act, primary authority and responsibility for dealing with the event belongs to the commander and risk manager; this event is beyond the scope of the PSP. The PSM will coordinate a review of the systems and processes implicated in the actual or potential intentional unsafe act, to include conducting an RCA, if applicable, but will defer to the separate command investigation with respect to the culpability of any person involved in the event.

(3) External reporting requirements. All incidents meeting the definition of an SE must be reported to the USAMEDCOM, and those events that meet the criteria for review by the JCAHO will be appropriately reported to that organization. External reporting of the PS event is the responsibility of the MTF commander (or his/her designee) and includes notification of--

(a) The USAMEDCOM PSC. All incidents meeting the definition of an SE and those that result in serious patient harm must be reported to the USAMEDCOM PSC within 72 hours of identification of the event. USAMEDCOM Form 732-R, Sentinel

Event Report Worksheet (appendix C), will be completed and transmitted by facsimile, electronic mail, or other electronic means of communication to the USAMEDCOM PSC. The MTF will also electronically notify its RMC of the occurrence of an SE.

(b) The JCAHO. All SEs that are reviewable by the JCAHO, as listed in paragraph 12b(3), must be reported to the JCAHO within 5 working days of the identification of the event. The appropriate documentation as required in current JCAHO guidance ( [http://www.jcaho.org/sentinel/se\\_form.html](http://www.jcaho.org/sentinel/se_form.html) ) will be completed and forwarded by facsimile transmission or commercial overnight delivery service to the JCAHO Office of Quality Monitoring, 1 Renaissance Boulevard, Oakbrook Terrace, IL 60181. No patient or caregiver identifiers will be used when reporting an SE to the JCAHO.

**13. PS EVENT CLASSIFICATION.** The PSM is responsible for reviewing and categorizing all reported PS events according to current DOD guidance as contained in this regulation. The SAC methodology categorizes each PS event using a 1-3 risk scoring scale as follows: 1 = low risk; 2 = moderate risk; and 3 = high risk. The SAC score methodology identifies the level of PS event analysis appropriate to the incident being considered.

a. SAC scoring of each PS event is based on the severity of the incident and its probability of recurrence. While there is some degree of subjectivity and individual judgment involved in this classification methodology, it provides organizations a standardized process for prioritizing actions and applying facility resources where there is the greatest opportunity to improve safety.

b. MTFs are encouraged to proactively evaluate and analyze any event, regardless of SAC score, that presents significant potential for future recurrence. It should be noted that the SAC score is extremely useful when evaluating close calls/near misses. Close calls generally occur more frequently than actual adverse events. Thus, proactive analyses of a close call provide an ideal opportunity to implement system or process improvements without having to experience an actual adverse event. With a close/near miss, the decision to charter a formal RCAT is at the discretion of MTF leadership.

(1) SAC 1 and 2 no-harm events. All SAC 1 and SAC 2 close calls and/or actual PS events with no harm to the patient will be entered into the MTF PS database. Monthly review and analyses for trends and/or process improvement opportunities will be conducted. The PS committee/functional team will review, prioritize, monitor, and track the effectiveness of all actions implemented.

(2) SAC 2 patient harm events. All SAC 2 events that result in harm to the patient will be reviewed by the PSM and the DCCS, or designee, to identify the appropriate level of event analysis warranted. If necessary, the USAMEDCOM PSC will be consulted to assist in identifying the best course of action for SAC 2 event management.

(3) SAC 3. SEs that are reviewable by the JCAHO and all other SAC 3 actual PS events require an RCA. For close calls/near misses with a potential SAC 3 score, the decision to charter an RCAT is at the discretion of the MTF leadership. SEs that are reviewable by the JCAHO include--

(a) All events resulting in an unanticipated death or major permanent loss of function (unrelated to the natural course of the patient's illness or underlying condition).

(b) Suicide in a 24-hour care setting.

(c) Infant abduction or discharge to the wrong family.

(d) Rape of a patient.

(e) Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities.

(f) Surgery on the wrong patient, the wrong body part, and/or the wrong site.

**14. PS EVENT ANALYSIS.** Event analysis assists in the discovery of the root causes and/or contributing factors associated with the PS event. Tracking and trending of data elements allows the PSM to identify familiar trends or circumstances so that system or process issues can be identified and improved. Levels of analyses include aggregate review and RCA.

a. Aggregate review analyses. Aggregate review consists of examining data elements for common trends or patterns within the group. The use of an aggregated review serves two important purposes. It allows wider applicability of the analyses (i.e., trends or patterns that were not noticeable in an individual case analysis become more obvious as the number of cases increases). In addition, it more clearly defines specific data elements in a recurring problem and encourages prudent use of the time and expertise of the MTF staff associated with evaluation and corrective action.

(1) Falls and medication errors in which no serious patient injury resulted will be analyzed on a quarterly basis using an aggregate review.

(2) Completed aggregate analyses will be forwarded to the USAMEDCOM PSC at the following address: Commander, USAMEDCOM, ATTN: MCHO-Q, 2050 Worth Road, Fort Sam Houston, TX 78234-6010, within 45 days following the end of the quarter. A follow-up after-action report identifying the effectiveness of all system and process improvements will be forwarded to the USAMEDCOM PSC 6 months after the aggregate analyses submission.

b. Root cause analysis. An RCA must be conducted and an action plan completed for all actual SAC 3 PS events and those that meet the definition of an SE. The MTF



commander, in consultation with the DCCS and PSM, will designate and formally charter an RCAT to conduct a thorough and credible RCA. The RCAT will conduct the RCA according to current USAMEDCOM guidance to facilitate standardization of data element collection and event analysis across the MHS.

(1) An RCA is the process for identifying the basic and/or contributing causal factor(s) associated with PS events. The review is interdisciplinary and includes those who are closest to the process, but typically not those directly involved in the specific event. (Note: Those individuals directly involved in the event will be consulted for event-related information.) The RCA focuses on systems and processes, not individual performance. The analysis asks "what" and "why" until all aspects of the process are reviewed and all contributing factors have been determined. It identifies changes that could be made in systems and processes to improve performance and to reduce the risk of adverse events, or the recurrence of close calls, with the ultimate goal of reducing and/or eliminating patient harm.

(2) If, in the course of conducting an RCA, it is determined the PS event is the result of an intentional unsafe act, deliberate gross negligence/reckless behavior, and/or possible criminal activity, the event shall be reported to the appropriate command authorities for investigation (paragraph 8f).

(3) The MTF risk manager and a legal advisor from the OCJA or the servicing OSJA will be notified of all SEs and may participate in the process of conducting the RCA, if appropriate.

c. RCA action plan. Once the RCA has been completed, a detailed action plan must be developed to enumerate the risk reduction strategies that the organization intends to implement to prevent the recurrence of similar events. The action plan should address responsibility for implementation, oversight, pilot testing (if appropriate), timelines, and the specific metrics to be employed in evaluating the effectiveness of the actions taken.

d. RCA and action plan review. The RCA and associated action plan for an SE will be submitted for review as follows:

(1) By the USAMEDCOM. A copy of the completed RCA and the action plan will be provided to the USAMEDCOM PSC within 45 calendar days of the MTF's discovery of the occurrence of an SE. Commercial overnight delivery service is authorized for this purpose.

(2) By the JCAHO. MTF commanders will select one of three alternatives to allow JCAHO review of the RCA and the action plan for a JCAHO-reviewable SE--

(a) Direct release of the RCA and action plan to the JCAHO using certified/return receipt mail or commercial overnight delivery service.

(b) Review of the RCA and the action plan delivered to JCAHO headquarters by MTF/dental treatment facility (DTF) staff then returned to the MTF/DTF immediately after review. A request for review by appointment must be received by the JCAHO at least 15 days prior to the due date for completion of the RCA and the action plan.

(c) An on-site visit by a specially trained surveyor to review the RCA and the action plan. A request for on-site review must be received by the JCAHO at least 15 days prior to the due date for completion of the RCA and the action plan.

e. Action plan follow-up review. Six months following the RCA submission, a follow-up after action report that addresses the effectiveness of the improvements implemented by the organization will be forwarded to the USAMEDCOM PSC, Commander, USAMEDCOM, ATTN: MCHO-Q, 2050 Worth Road, Fort Sam Houston, TX 78234-6010. A copy will be provided to the JCAHO, Office of Quality Monitoring, 1 Renaissance Boulevard, Oakbrook Terrace, IL 60181.

**15. PS EVENT COMMUNICATION.** Commanders and all MTF staff are reminded that all data compiled as part of the PSP are QA information protected under 10 USC 1102 and must be marked "Quality Assurance protected document 10 USC 1102; Unauthorized Disclosure Carries \$5000 Fine." The authority for review of this protected information by the JCAHO and specifically authorized external agencies appears in 10 USC 1102.

a. The reporter of the PS event. Staff members and supervisors who submit PS event reports will receive timely feedback on the actions being taken as a result of their report. Prompt feedback to those who identify PS events has been credited in other reporting systems with being one of the cornerstones that establishes trust in the system. A timely response demonstrates the commitment on the part of the organization to the reporting effort. The nature of feedback to the individual can range from a simple acknowledgement that the event is under consideration to providing information about the corrective action that is planned/has been accomplished. This communication openly confirms the importance of the staff member's efforts to participate actively in organizational performance improvement.

b. Staff members involved in the PS event. Any staff member reporting and/or directly involved in a PS event that caused patient harm will receive support and assistance from his/her supervisor to facilitate the staff member's professional and emotional needs related to the PS event. Management efforts and activities will focus on improving the systems and processes that may have contributed to the PS event rather than disciplining those involved.

c. Patient/family affected by the event. In cases involving an unanticipated outcome of care, a qualified health care provider will inform the patient and/or his/her family member(s). This information is provided as a matter of policy and does not affect any

rights or obligations in legal or administrative proceedings. Under no circumstances will QA-protected information be released or provided to the patient/family member.

(1) The MTF commander, or designee, is responsible to ensure that provider and patient/family member communication takes place. To ensure continuity, the initial disclosure of information and subsequent discussions with the patient and/or family should be handled, whenever possible, by the primary care manager or attending physician responsible for the patient's overall care. During the initial communication, and at subsequent planned discussions, at least one other hospital staff member should be present. For discussions anticipated to be complex or difficult, the patient/family member may have another individual with them for support. The designated primary communicator will document in the patient's medical record what was communicated to the patient/family, the patient/family member's response, and any other pertinent discussion.

(2) In most cases, facts surrounding the PS event that affect the patient can and should be disclosed to the patient/family member by the provider.

(3) Any specific questions relative to disclosure of information associated with unanticipated adverse outcomes should be referred to the MTF OCJA or OSJA.

d. Safe/best practices and lessons learned. To facilitate a successful AMEDD PSP, it is imperative that all levels of personnel (MTF/corporate) learn from PS-related incidents by being informed of the system/process contributing factors that resulted in patient harm.

(1) The MTF PSM will provide feedback to all levels of MTF staff on reported PS events and lessons learned. These include PS improvement strategies and best/safe practices to be implemented at the unit/clinic level to prevent recurrence of similar events in the future.

(2) The USAMEDCOM PSC and AFIP will identify trends and opportunities for improvement, to include safe/best practices and implementation strategies identified through corporate and MHS PS event analysis. This information will be distributed using the USAMEDCOM PSC and AFIP web sites and other appropriate communication mechanisms.

(3) The MTF PSM will also receive regular electronic and telephonic feedback and support from the USAMEDCOM PSC regarding SEs, RCAs, aggregate analyses, and the development and evaluation of RCA action plans.

## **16. PS EDUCATION AND TRAINING.**

a. MTF staff. All assigned personnel will receive PS education and training during their initial hospital orientation and on an annual and as-needed basis, regarding job-related aspects of PS and staff-specific roles and responsibilities to actively support PS policy. PS-related topics include, but are not limited to--

- (1) An overview of the AMEDD PSP and MTF program execution.
- (2) Roles and responsibilities in reporting PS events.
- (3) Patient education requirements.
- (4) Effective communication and teamwork strategies.

b. Patients/family members. Health care beneficiaries and family members will receive education about their role in helping to facilitate the safe delivery of care. Topics will include general information about the PSP and the ways beneficiaries/family members can effectively participate in PS.

c. RCAT members. Personnel selected to serve on an RCAT will receive “just-in-time” training which includes RCAT process guidance and team rules, effective interview techniques, and the appropriate use of RCA tools (e.g., flow charts, cause and effect diagrams).

**17. PS METRICS.** The effectiveness of the PSP will be evaluated at all levels using standardized metrics. Measuring the progress of this newly implemented program is key to its success as a dynamic, meaningful program. As the PSP matures, the goals will be updated to ensure that different aspects of the program are addressed according to current corporate guidance. As the AMEDD PSP evolves, the evaluation metrics are likewise expected to change. The current PS metrics are listed in appendix D. These metrics, as identified, relate to the PSP goals at the MTF level for the first year of the program.

**18. PS REPORTING.** Internal and external reporting related to the PSP includes--

a. The MTF executive committee.

(1) Minutes/reports from the PS committee/functional team will be submitted to the MTF executive committee per established MTF guidelines. These minutes/reports will summarize the results of MTF organizational/high-risk area assessments, PS events, and progress on all action plans implemented as a result of a PS event analysis. The PS committee/functional team will also provide recommendations to the MTF leadership for improvements to specific PS processes, PS initiatives, and other organizational changes, as appropriate.

(2) The annual Clinical Quality Management Program report submitted for review by the executive committee will include a PSP evaluation and summary of the MTF organizational/high-risk area assessments, PS events, and progress on all action plans implemented as a result of a PS event analysis. This report will be forwarded through the RMC commander to USAMEDCOM PSC with internal copy provided to the USAMEDCOM PSC.

b. The USAMEDCOM PSC. A quarterly PS report utilizing the USAMEDCOM-provided format will be forwarded electronically to the USAMEDCOM PSC. The report will include requested aggregate data and summarize the results of all MTF PS event analysis, progress on action plans implemented, and the effectiveness of these actions, as appropriate. The quarterly report is due NLT 45 days after the end of each fiscal year quarter.

**19. CONFIDENTIALITY OF MEDICAL QUALITY ASSURANCE INFORMATION.** As with other medical QA documents, any information, records, reports, minutes, and other documents directly associated with PS activities are protected under 10 USC 1102. In discussing medical information with family members, MTF personnel shall also comply with other applicable restrictions on nonconsensual disclosures, including those under the Privacy Act, 5 USC 552a; DOD Regulation 5400.11-R ; and Service regulations. As a general rule under the Privacy Act, information regarding a patient's condition shall not be provided to others without the patient's consent.

## **Appendix A**

### **References**

#### **Section I**

##### **Required Publications**

###### **AR 25-400-2**

The Modern Army Recordkeeping System (MARKS)

###### **AR 40-61**

Medical Logistics Policies and Procedures

###### **AR 40-68**

Quality Management

###### **DOD Directive 6040.37**

Confidentiality of Medical Quality Assurance (QA) Records, 9 July 1996

###### **DOD Instruction 6025.17**

Military Health System Patient Safety Program, 16 August 2001

###### **DOD Regulation 5400.11-R**

Department of Defense Privacy Program

###### **United States Code (USC), Title 10, Section 1102 (10 USC 1102)**

Confidentiality of Medical Quality Assurance (QA) Records 1987

###### **Unnumbered publication**

Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Accreditation Manual: Comprehensive Accreditation Manual for Hospitals (2001)

#### **Section II**

##### **Related Publications**

###### **Floyd D. Spence Defense Authorization Act for Fiscal Year 2001**

(Sections 742 and 754)

###### **Institute of Medicine Report #1**

To Err is Human: Building a Safer Health System. Washington, DC: National Academy Press (1999)

###### **Institute Of Medicine Report #2**

Crossing the Quality Chasm: A New Health System for the 21<sup>st</sup> Century. Washington, DC: National Academy Press (2001)

**Marx, David**

Patient Safety and the “Just Culture”: A Primer for Health Care Executives. Medical Event Reporting System for Transfusion Medicine. New York: Trustees of Columbia University (2001)

**Spath, Patrice L.**

Error Reduction in Health Care—A Systems Approach to Improving Patient Safety. San Francisco: Jossey-Bass (2000)

## Appendix B

### Patient Safety Program Safety Assessment Code Matrix

#### Severity Categories

Key factors for the severity categories are: extent of injury; length of stay; and level of care required for remedy. The four categories below apply to actual adverse events.

For actual close calls/adverse events, assign severity based on the patient's actual condition. Some incidents that occur may have such an overwhelming potential for a catastrophic event that an RCA will also be necessary, but that determination will be left to the discretion of the MTF.

<b>Catastrophic</b>	<b>Major</b>
<p><b>Patients with actual:</b></p> <p>Death or major permanent loss of function (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying condition (i.e., acts of commission or omission).</p> <p>Suicide (inpatient or outpatient).</p> <p>Rape.</p> <p>Hemolytic transfusion reaction.</p> <p>Surgery/procedure on the wrong patient or wrong body part.</p> <p>Infant abduction or infant discharge to the wrong family.</p> <p>Death or major permanent loss of function that is a direct result of injuries sustained in a fall, or associated with an unauthorized departure from an around-the-clock treatment setting, or the result of an assault or other crime.</p>	<p><b>Patients with actual:</b></p> <p>Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying conditions (i.e., acts of commission or omission).</p> <p>Disfigurement.</p> <p>Surgical intervention required.</p> <p>Increased length of stay or level of care of 3 days or more.</p>
<b>Moderate</b>	<b>Minor</b>
<p><b>Patients with actual:</b></p> <p>Increased length of stay or higher level of care for less than 3 days.</p>	<p><b>Patients with actual:</b></p> <p>No increased length of stay or increased level of care.</p>



### **Probability of Recurrence**

Like the severity categories, the probability of recurrence applies to actual adverse events and close calls.

In order to assign a probability rating for an adverse event or close call, it is ideal to know how often it occurs at your facility. Sometimes, the data will be easily available because it is routinely tracked (e.g., falls with injury, medication errors, etc.). Sometimes, getting a feel for the probability of events which are not routinely tracked will mean asking for a quick or informal opinion from staff most familiar with those events. Sometimes it will have to be your best educated guess.

**High** – Likely to occur immediately or within a short period of time.

**Medium** – Likely to occur several times in 1 to 2 years.

**Low** – May happen at intervals greater than 2 years.

### **How the SAC Matrix Looks**

<b>PROBABILITY</b>	<b>SEVERITY</b>			
	<b>Catastrophic</b>	<b>Major</b>	<b>Moderate</b>	<b>Minor</b>
<b>High</b>	<b>3</b>	<b>3</b>	<b>2</b>	<b>1</b>
<b>Medium</b>	<b>3</b>	<b>2</b>	<b>1</b>	<b>1</b>
<b>Low</b>	<b>3</b>	<b>2</b>	<b>1</b>	<b>1</b>

### **How The SAC Matrix Works**

When a severity category is paired with a probability category for either an actual event or close call, the result is a ranked matrix score (3 = highest risk, 2 = intermediate risk, 1 = lowest risk). These ranks, or SACs, can then be used for comparative analyses and for deciding who needs to be notified about the event.

### **Notes**

1. All known reporters of events, regardless of SAC score (1, 2, or 3), will receive appropriate and timely feedback.
2. The PSM (or designee) will refer adverse events or close calls (related solely to staff, visitors, or equipment/facility damage) for assessment and resolution to relevant facility experts or services on a timely basis.
3. A quarterly aggregated analyses may be used for two types of calls (this includes all events or close calls other than actual SAC 3s, since all actual SAC 3s require an individual RCA). These two types are falls and medication errors. The use of aggregated analyses serves two important purposes. First, greater utility of the analyses (i.e., trends or patterns not noticeable in individual case analysis) are more likely to show up as the number of cases increases. Second, it makes wise use of the RCA team's time and expertise.

Of course, the facility may elect to perform an individual RCA rather than aggregated review on any adverse event or close call that they think merits that attention, regardless of the SAC score.

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\*29 CFR 1960.70 requires each Federal agency to notify the Occupational Safety and Health Administration within 8 hours of a work-related incident which results in the death of an employee or the inpatient hospitalization of three or more employees.

**Appendix C**

**Sentinel Event Report Worksheet (MEDCOM Form 732-R)**

**SENTINEL EVENT REPORT WORKSHEET**

For use of this form see MEDCOM Reg 40-41

**SECTION I - DEMOGRAPHICS**

1. MEDICAL TREATMENT FACILITY (Name and Location)		2. CASE NUMBER
3. MTF POC (Last Name, First, MI)	4. TELEPHONE and FAX NUMBERS	5. DATE (dd-mmm-yy)

**SECTION II - EVENT IDENTIFICATION**

DIRECTIONS: All incidents meeting the current Joint Commission on Accreditation of Healthcare Organizations (JCAHO) definition of a sentinel event will be reported to the USAMEDCOM, Patient Safety Center (PSC). This form will be completed and transmitted by facsimile (FAX) to 210-221-7118, or other electronic means. Other requirements of the JCAHO related to a sentinel event will also be followed.

**6. TYPE OF EVENT (Check all that apply):**

- ☐ Unanticipated death or, ☐ Major permanent loss or, ☐ Serious Physical injury or ☐ Serious psychological injury not related to natural course of patient's illness or underlying condition.
- Preliminary information indicates this is related to ☐ Anesthesia ☐ Delay in Treatment/Transfer ☐ Laboratory
- ☐ Equipment ☐ Restraints ☐ Fall ☐ Environment of Care (e.g., Fire, Hazardous Material, Medical Gas, Security, Utilities)
- ☐ Operative/Other Invasive Procedure ☐ Medication ☐ Obstetric Complication
- ☐ Other (Specify) \_\_\_\_\_
- ☐ Suicide in a 24-hour facility
- ☐ Infant abduction, or ☐ Infant discharged to wrong family.
- ☐ Rape
- ☐ Hemolytic transfusion reaction due to administration of blood or blood products having major blood group incompatibilities
- ☐ Surgery on the wrong patient, ☐ Surgery on the wrong site (side/level/part), or ☐ The wrong surgery/procedure performed
- ☐ A close call (near miss), a recurrence of which presents a significant chance of a serious adverse outcome
- ☐ Other, (Please explain briefly) \_\_\_\_\_

**SECTION III - TIMELINES****7. REPORTING REQUIREMENTS. From discovery date of incident the following will apply:**

- a. 72 hours to report incident to USAMEDCOM PSC.
- b. Five (5) days to report to JCAHO.
- c. 45 days to transmit completed root cause analysis (RCA) and action plan to the JCAHO and USAMEDCOM PSC.

**8. RECORD OF EVENTS.**

DATE	ACTION
	a. Incident identified.
	b. Root Cause Analysis Team Chartered.
	c. Incident reported electronically or telephonically to USAMEDCOM PSC.
	d. Regional Medical Command (RMC) notified.
	e. Initial report of incident to JCAHO (if applicable).
	f. RCA and action plan to USAMEDCOM PSC.
	g. RCA and action plan to JCAHO (Select one):
	<input type="checkbox"/> Certified mail/overnight delivery
	<input type="checkbox"/> Review at JCAHO central office
	<input type="checkbox"/> On-site visit by JCAHO representative

**SECTION IV - USAMEDCOM ACTION**

9a. USAMEDCOM ACTION OFFICER (Name)	9b. USAMEDCOM LOG NUMBER
<b>10. FOLLOW-UP WITH MTF.</b>	
DATE	ACTION

The information placed on this form is confidential and privileged IAW 10 U.S.C. 1102  
**UNAUTHORIZED DISCLOSURE CARRIES A \$5,000 FINE.**  
DO NOT FILE OR REFER TO THIS FORM IN PATIENT RECORD. REPORT EVENT TO SUPERVISOR/DEPARTMENT CHIEF IMMEDIATELY.

## **Appendix D**

### **Patient Safety Program Metrics**

Quantitative standards will be established to evaluate the effectiveness of the PSP on an ongoing basis. Each facility should define such metrics in accordance with baseline data that have been obtained either through the PSC or through local data analyses. As the program evolves and matures, the goals/objectives of the program will change. Metrics used to measure program effectiveness should be modified to reflect these changes. As a minimum, each facility will implement the following during the first year of PSP implementation to measure program effectiveness.

(1) The AMEDD PSP is in place (i.e., 100 percent compliance) as evidenced by the following activities. The organization is completing the MEDCOM PSP-identified PS risk assessment(s), establishing the PS database, conducting an aggregate review, and performing a prospective analysis and RCA.

(2) The organization is actively transitioning to a culture of safety and openly discussing PS issues as evidenced by a median score in the climate survey reassessment of 10 percent over the individual MTF baseline.

(3) There is a 10 percent increase in close call/near miss reporting each quarter after the first quarter (e.g., the baseline) to be measured by the number of close calls/near misses reported over the total number of PS events.

(4) One system improvement and/or safe/best practice is identified, implemented, and monitored for effectiveness.

## **GLOSSARY**

### **Section I Abbreviations**

#### **AMEDD**

Army Medical Department

#### **AFIP**

Armed Forces Institute of Pathology

#### **DCA**

deputy commander for administration

#### **DCCS**

deputy commander for clinical services

#### **DCN**

deputy commander for nursing

#### **DOD**

Department of Defense

#### **DODI**

Department of Defense Instruction

#### **DTF**

dental treatment facility

#### **JCAHO**

Joint Commission for Accreditation of Healthcare Organizations

#### **MHS**

military healthcare system

#### **MTF**

military treatment facility

#### **OASD(HA)**

office of Assistant Secretary of Defense for Health Affairs

#### **OCJA**

office of the center judge advocate

#### **OSJA**

office of staff judge advocate

**PCE**

potentially compensable event

**PS**

patient safety

**PSC**

Patient Safety Center

**PSM**

patient safety manager

**PSP**

Patient Safety Program

**PST**

patient safety team

**QA**

quality assurance

**QM**

quality management

**RCA**

root cause analysis

**RCAT**

root cause analysis team

**RM**

risk management

**RMC**

regional medical command

**SAC**

safety assessment code

**SE**

sentinel event

**SOC**

standard of care

**TSG**

The Surgeon General

**USAMEDCOM**

U.S. Army Medical Command

**USC**

United States Code

**Section II**

**Terms**

**Action plan**

The end product of an RCA that identifies the risk reduction strategies the organization intends to implement to prevent the recurrence of similar adverse events in the future.

**Actual event**

A situation or circumstance that did occur either with or without harm to the patient.

**Adverse event**

An adverse event is an occurrence or condition associated with the provision of health care or services that may or may not result in harm to the patient/beneficiary. Adverse events may be due to acts of commission or omission. Incidents such as patient falls or improper administration of medications are also considered adverse events even if there is no harm or permanent effect on the patient.

**Aggregate**

To combine standardized data and information collected over time.

**Aggregate review**

The process of analyzing recurring incidents, events, or close calls (near misses) for trends and patterns. This information is utilized by the organization for process improvement interventions.

**Close call**

A close call is an event or situation that could have resulted in harm to a patient, but did not, either by chance or through timely intervention. The event was identified and resolved before reaching the patient. Such events have also been referred to as “near miss” incidents. Because close calls generally occur more frequently than actual adverse events, proactive analysis of close calls provides tangible opportunity to improve the system without having to experience an actual adverse event. Leaders should emphasize the value of close calls and encourage and acknowledge staff for reporting these opportunities for improvement.

**Contributing factors**

Additional reasons, not necessarily the most basic reasons, for an event to be less than ideal, as planned, or as expected. Contributing factors may apply to individuals, systems operations, or the entire organization.

**Data**

Material facts or clinical observations that have not been interpreted.

**Evaluation**

Analysis of collected, compiled, and organized data pertaining to important aspects of care. Data are compared with predetermined, clinically valid criteria; variations from criteria are determined to be acceptable or unacceptable; and problems or opportunities to improve care are identified.

**Gross negligence**

See Reckless conduct.

**Intentional unsafe act**

Any alleged or suspected deliberate act or omission by a provider, staff member, contractor, trainee, or volunteer pertaining to a patient that involves--a criminal act; a purposefully unsafe act; patient abuse; or an event caused or affected by drug or alcohol abuse. Intentional unsafe acts are matters for law enforcement, the military or civil service disciplinary systems, or an administrative investigation, and are not within the definition of an adverse event.

**Near miss**

An event or situation that could have resulted in harm to a patient but did not, either by chance or through timely intervention. The event was identified and resolved before reaching the patient. Such events have also been referred to as "close call" incidents.

**ORYX**

A JCAHO initiative that integrates outcomes and other performance measurement data into the accreditation process.

**Patient safety event**

An incident or error that occurred (actual event), or almost occurred (close call/near miss), that caused, or had the potential for causing, harm to a patient.

**Quality improvement**

An approach to the continuous study and improvement of the processes of providing health care services to meet the needs of individuals and others. Synonyms include continuous quality improvement, continuous improvement, organization-wide PI, and total quality management.



**Rape**

Sexual intercourse by a person, executed by force and without consent of the victim. It may be committed on a victim of any age. Any penetration, however slight, is sufficient to complete the offense. "Any person subject to this chapter who commits an act of sexual intercourse by force or without consent, is guilty of rape." (Article 120, UCMJ)

**Reckless conduct**

Involves conscious disregard of risk. Also referred to as gross negligence. Reckless conduct differs from "negligent conduct" in intent. Negligence is the failure to recognize a risk that should have been recognized while reckless conduct is a conscious disregard of a known risk. NOTE: The legal definitions may vary slightly.

**Risk assessment**

A method used to proactively evaluate the probability of a patient safety event in order to minimize the risk of the event actually occurring.

**Risk management**

Clinical and administrative activities that organizations undertake to identify, evaluate, and reduce the risk of injury to patients, staff and visitors, and the risk of financial loss to the organization. It involves identification of risk potential, prevention of risk exposure, and the management of real or potential adverse incidents and medical malpractice claims.

**Root cause**

The most basic reason that a situation did not turn out ideally, as planned, or as expected.

**Root cause analysis**

A process for identifying the basic or contributing causal factor(s) associated with an adverse event or close call. The review is interdisciplinary and includes those who are closest to the process. It focuses on systems and processes, not individual performance. The analysis asks "what" and "why" until all aspects of the process are reviewed, and all contributing factors have been determined. It identifies changes that could be made in systems and processes to improve performance and reduce the risk of adverse events or recurrence of close calls.

**Root cause analysis team (RCAT)**

The group identified by the MTF/DTF commander to develop the RCA and Action Plan. The RCAT should include leaders of performance improvement/QM, RM, nursing and patient care services; the medical staff; the department head or supervisor of the area in which the event occurred; administrative staff (e.g., DCA, RM, MTF Safety); a Staff Judge Advocate representative; and others as necessary depending on the event. RCAT members will be trained and knowledgeable in the SE process.

**Safety assessment code (SAC) matrix**

A risk assessment tool that considers the severity of an adverse or near miss event together with the probability of the event's recurrence. The score, or SAC, assigned to the event determines the type of action that should be taken to address the event (i.e. RCA, intense analysis, or no action). See appendix B.

**Sentinel event**

A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof that is not related to the natural course of the patient's illnesses or underlying condition. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof," includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and proactive response on the part of the organization.

**The proponent of this publication is the Quality Management Directorate. Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) to Commander, U.S. Army Medical Command, ATTN: MCHO-Q, 2050 Worth Road, Fort Sam Houston, TX 78234-6010.**

FOR THE COMMANDER:



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